

**SYSTEM AND METHOD FOR SIMULATION AND MODELING OF
BATCH PROCESS MANUFACTURING FACILITIES
USING PROCESS TIME LINES**

Abstract

5 A system and method for the simulation and modeling of
biopharmaceutical batch process manufacturing facilities using process time lines
is described herein. The system employs a four-field delimited string code which
specifies the unit identifier code and the iteration value for each of the three levels
10 of scheduling cycle "Unit Operation Cycles," "Unit Operation Cluster Cycles,"
and "Batch Cycles"-- of the biopharmaceutical drug production process being
modeled. The method includes the step of selecting a sequence of unit operations
wherein each of the sequence of unit operations has an identifier code. Next, a
set of scheduling cycles is selected for each of the sequence of unit operations.
15 A master table is then referenced, using the identifier code, to obtain operational
parameters for each of the sequence of unit operations. A block flow diagram is
then generated using the sequence of unit operations and the operational
parameters. The method further includes generating a process time line using the
operational parameters, the block flow diagram, and the set of scheduling cycles
20 for each of the sequence of unit operations. The process time line--a time line for
the beginning and ending times of each unit operation and its associated tasks for
the entire biopharmaceutical drug production process--is used as a tool for batch
processing and facility design.

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